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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,990

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Scott Cunningham

2850

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EXAMINER

RYCKMAN, MELISSA K

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/618,990	Applicant(s) CUNNINGHAM ET AL.	
	Examiner MELISSA RYCKMAN	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 12-22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to argument filed 10/22/08.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9,12-22,24, and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The originally filed application does not include "the needle point being displace a predetermined distance with respect to the longitudinal axis and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension "xt" of the enlarged transition portion." Because the language regarding the dimension of "xt" can be interpreted to be the entire x dimension of the enlarged transition portion, not just the difference of "x1" and the enlarged transition portion (such as "H" as seen in Fig. 5 of the current application). The applicant should further clarify "xt" to overcome this rejection.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-9, 12-22, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alchas (U.S. Patent No. 4,537,593), and further in view of Allen (U.S. Patent No. 5,403,344) and Gravlee, Jr. (U.S. Patent No. 5,733,266).

Claims 1, 12 and 13:

Alchas teaches a surgical needle, which comprises:

- an elongated substantially linear needle body (31) defining a central longitudinal y-axis along which the needle body extends and transverse x and z-axes, the needle body including a central shaft portion (33)
- a first suture end portion (36) for attachment to a suture (capable of attaching to a suture) and a second needled end portion (39) for penetrating tissue
- the needled end portion (39) further defining an enlarged transition portion adjacent the central shaft section with at least an x-dimension "xt" greater (portion near 4 in Fig. 3) than a corresponding x-dimension "xl" of the central shaft (diameter of 33)

Alchas does not have the needled end portion having three sides which intersect to define three cutting edges and terminate at a needle point, each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side. However Allen teaches the needled end portion

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having three sides (20) which intersect to define three cutting edges and terminate at a needle point (Fig. 3), each side including one sole pair of planar surface portions arranged in oblique relation to define a general concave appearance to each side (Fig. 4). It would have been obvious to one of ordinary skill in the art to modify the invention of Alchas with the needle ended portion of Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

Alchas and Allen do not specify some of the geometry as specified in the claims, however Gravlee teaches:

- the needle point (28) being displaced a predetermined distance with respect to the longitudinal axis (Fig. 4) and wherein the predetermined distance is less than $\frac{1}{2}$ the x-dimension "xt" of the enlarged transition portion (Fig. 4)
- at least one side of the needled end portion being displaced by an angle alpha from a plane parallel to the longitudinal axis (Fig. 4), the angle alpha being between about 2° , and about 10° , wherein the side of the needled end portion displaced by angle alpha from the plane parallel to the longitudinal axis has a substantially continuous slope between the enlarged transition portion and the needle point

It would have been obvious to one of ordinary skill in the art to use the geometry of Gravlee with the device of Alchas and Allen, as the angles blade increases the surface area of the blade and aids in cutting the tissue.

Claim 2:

Alchas and Allen teach the planar surface portions of each side are arranged to intersect along a median plane bisecting a respective side to define a substantially symmetrical concave appearance to the respective side (Allen, Fig. 3).

It would have been obvious to one of ordinary skill in the art to modify the invention of Alchas with the needle ended portion of Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

Claims 3, 14 and 15:

Alchas teaches the enlarged transition portion defines a z-dimension "zt" (portion from 35 to near 36 in Fig. 3) greater than or equal to a corresponding z-dimension "zl" of the central shaft portion (Fig. 3).

Claim 4:

Alchas teaches the x-dimension "xt" (Fig. 3, diameter of proximal portion of 31) and z-dimension "zt" (portion from 35 to near 36 in Fig. 3) correspond to the height and width respectively of the transition portion of the needle end portion.

Claims 5-7:

Alchas and Allen teach the planar surface portions of each side intersect to define an included angle ranging from about 160° to about 175° (20, Allen, Fig. 2), the included angle is about 170° (20, Allen, Fig. 2), two of the cutting edges intersect at the needle point and define an angle of about 22° to about 25° (Fig. 4, Allen).

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It would have been obvious to one of ordinary skill in the art to modify the invention of Alchas with the needle ended portion of Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

Claim 8:

Alchas and Allen teach the central shaft portion (Alchas, 33) defines a distal shaft transition portion (near 4, Fig. 3, Alchas) adjacent the needled end portion, the distal shaft portion defining a cross-section of general triangular character (cross section near 4 in Fig. 3, Alchas).

Claim 9:

Alchas and Allen teach the distal shaft portion includes three planar surfaces interconnected by rounded surfaces (Allen, Fig. 4, 26 is rounded). It would have been obvious to one of ordinary skill in the art to modify the invention of Alchas with the needle ended portion of Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

Claims 16 and 18:

Alchas and Allen teach the x-dimension "xt" of the enlarged transition portion is defined between adjacent cutting edges (Fig. 3, Alchas).

Claims 17 and 19:

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Alchas and Allen teach the z-dimension "zt" of the enlarged transition portion is defined between adjacent cutting edges (Fig. 3, Alchas).

Claims 20 and 21:

Alchas and Allen teach each side of the needle end portion (Fig. 4, Allen) includes a single pair of first and second planar surface portions arranged in oblique relation (Allen, Fig. 2), the first and second planar portions being the pair of planar portions. Alchas and Allen teach each side of the needle end portion includes a single pair of first and second planar surface portions arranged in oblique relation (Allen, Fig. 2 and 4), the first and second planar portions being the pair of planar portions.

It would have been obvious to one of ordinary skill in the art to modify the invention of Alchas with the needle ended portion of Allen in order to minimize the surface area of the needle in contact with the skin in order to provide improved penetration performance, less tissue trauma and distortion and a reduced wound opening area.

Claims 22 and 25:

Alchas and Allen teach each cutting edge is substantially linear (Allen, Fig. 4, 20, substantially linear, Fig. 2).

Claim 24:

Alchas and Allen teach the needle body is adapted to assume a curved configuration (Allen, Fig. 1).

It would have been obvious to one of ordinary skill in the art to modify the invention of Alchas with the needle body of Allen as a curved needle aids in manipulating the needle within the body.

Response to Arguments

Applicant's arguments filed 10/22/08 have been fully considered but they are not persuasive. The applicant generally argues the following:

- The applicant disagrees with the 112 2nd rejection
- Gravlee Jr. does not teach the angle being between about 2 and 10 degrees
- Combining a non-coring needle assembly (Alchas) a hypodermic needle (Gravlee Jr.) and a surgical needle (Allen) is improper

The examiner disagrees with the applicant, as described above the language regarding the dimension "xt" leads to multiple interpretations including "xt" being the entire x-dimension (such as "H" as seen in Fig. 5 of the current application) of the enlarged transition portion, not only the difference. Graylee Jr. teaches **about** 2-10 degrees, as the word about includes more angles than 2-10 degrees.

Combining different types of needles is proper, as these needles can all be used for multiple functions and are well known in the art to combine multiple needles.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773